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EXAMINER

FOREMAN, JONATHAN M

ART UNIT

PAPER NUMBER

3736

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |  |                                       |  |
|------------------------------|--|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/025,668   | <b>Applicant(s)</b><br>GRIFFIN ET AL. |  |
|                              | <b>Examiner</b><br>JONATHAN ML FOREMAN | <b>Art Unit</b><br>3736               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,5-16,20,24-41,44 and 45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5-16,20,24-41,44 and 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Specification*

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the specification fails to provide proper antecedent basis for the glass transition temperature being greater than the body temperature of the patient.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 5 – 16 and 37 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 1 states "an elongate core wire comprising a portion formed of a super elastic nickel titanium alloy which is **not independently shapeable**". However, the specification fails to describe how to make a core formed of a super elastic nickel titanium alloy that is not capable of being shaped. Although, super elastic nickel titanium alloys may have a high kink resistance, provided enough force permanent deformation can take place.

### *Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the

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subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 5, 6, 20, 24, 25, 36 - 41, 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,368,049 to Raman et al. in view of U.S. Patent No. 6,024,764 to Schroepfel.

6. In regards to claims 1, 5, 6, 20, 24, 25, 36 - 41, 44 and 45, Raman et al. disclose an elongate core wire comprising a super elastic nickel titanium alloy (Col. 4, lines 49 – 51; Col. 5, lines 15 – 16) and having a tapered portion (Figure 1). Raman et al. disclose a formable cladding in continuous contact with the core wire that is more stiff than the distal tapered portion of the guidewire which it surrounds to allow a physician to impart a shape to the distal tip (Col. 5, lines 6 – 14). However, Raman et al. fail to disclose the cladding being a shape memory polymer jacket, wherein the shape memory polymer is one from a subset of polymers which are characterized by their responsiveness to heating at or above a glass transition temperature of the shape memory polymer in order to independently transform the shape memory polymer between a first and second shape. Schroepfel discloses a guiding element for positioning within a patients body (Col. 5, lines 12 – 15) including a polymer jacket being a shape memory polymer more stiff than the portion of the core wire which it surrounds (Col. 5, lines 41 – 57); wherein the shape memory polymer is one from a subset of polymers which are characterized by their responsiveness to heating at or above a glass transition temperature of the shape memory polymer in order to independently transform the shape memory polymer between a first and second shape, wherein the glass transition temperature is greater than the body temperature of the patient such that a curved shape imparted on the guiding element is maintained. Schroepfel discloses that any number of different types of tubular devices can include such a jacket (Col. 3, lines 53 – 57). It would have been obvious to one having ordinary skill in the

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art to modify the cladding as disclosed by Raman et al. to include a shape memory polymer jacket as taught by Schroepfel so the device can be shaped by a surgeon into a shape and subsequently reshaped if desired to allow for introduction into the patient's anatomy (Col. 5, lines 50 – 60) without having to worry about fractures forming in the cladding from repeated use.

7. Claims 7 – 16 and 26 - 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,368,049 to Raman et al. in view of U.S. Patent No. 6,024,764 to Schroepfel as applied to claims 1 and 20 above, and further in view of U.S. Patent No. 6,485,458 to Takahashi.

8. In reference to claims 7 – 16 and 26 - 35, Raman et al. in view of Schroepfel disclose a shape memory polymer surrounding a portion of the core wire being polynorborene, polyurethane and similar materials (Col. 7, lines 46 – 50), but fails to disclose the polymer being polycaprolactone, polymethylmethacrylate, PLLA, PLLA OGA, PL/D LA, PMMA, polyethylene, polyisoprene, styrene-butadiene or photocrosslinkable polymer. However, Takahashi discloses a shape memory polymer surrounding a core wire wherein the polymer consists of poluorbornen, styrene-butadiene, polyisoprene, polyester, polyolefin, acrylic and styrene-acrylic (Col. 5, lines 56 – 67). Takahashi teaches that other shape-memory materials can be used in addition to those disclosed. It would have been obvious to one having ordinary skill in the art at the time the invention was made use any shape memory polymer as taught by Takahashi in the device as disclosed by Raman et al. in view of Schroepfel in that Takahashi teaches that shape memory polymers are interchangeable. Additionally, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, replacing the shape memory polymer as disclosed by Raman et al. in view of Schroepfel with any other shape memory polymer is a design consideration within the skill of the art.

***Response to Arguments***

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. F./  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736